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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,282	08/21/2006	Danuta Ciok	P70807US0	1573
69289	7590	12/18/2009		
COLOPLAST A/S				
Attention: Corporate Patents				
Holtedam 1				
DK-3050 Humleback,				
DENMARK				
EXAMINER				
KIDWELL, MICHELE M				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
12/18/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@coloplast.com

dkbvd@coloplast.com

### Office Action Summary

**Application No.**

10/551,282

**Applicant(s)**

CIOK ET AL.

**Examiner**

Michele Kidwell

**Art Unit**

3761

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5, 9, 10, 13, 14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 9, 10, 13, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leise, Jr. (US 5,401,264) in view of EP 1 254 647

With respect to claims 1 and 13 – 14, Leise, Jr. (hereinafter “Leise”) discloses a one piece ostomy appliance comprising a bag having a front and rear wall with an opening disposed therein (figure 1), and an adhesive wafer (col. 2, line 67 to col. 3, line 3) having a hole alignable with the opening (figure 1), and including a first and second side wherein the second side includes first and second portions (figures 1 - 5) and an adhesive layer (col. 3, line 10) positioned to selectively secure the second portion of the wafer to the rear wall.

The difference between Leise and claim 1 is the provision that the second portion is unattached to the rear wall of the bag and that the adhesive layer includes a release liner.

Leise discloses that the attachment of the wafer to the edge of the rear wall may include resealable coupling means as set forth in col. 3, lines 7 – 14. In this case, the second portion may be selectively secured, permanently secured and/or unattached to the rear wall.

EP 1 254 647 (hereinafter ‘647) provides an ostomy appliance with a release liner covering the adhesive layer as set forth in the abstract.

It would have been obvious to one of ordinary skill in the art to provide the adhesive layer of Leise with a release liner because the use of such protects the adhesive surface prior to use as taught by ‘647 in col. 3, lines 4 – 6.

Inasmuch as the applicant has provided a “one piece” ostomy device (i.e., bag and wafer), the examiner contends that Leise in view of ‘647 provides the same.

Claims 4 – 5, 9 – 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leise, Jr. (US 5,401,264) in view of Thomas (4,865,594)

The difference between Leise and claim 4 is the provision that the ostomy appliance comprises a stiffening element.

Thomas provides the ostomy appliance with a stiffening element to which first and second parts of the bag are secured as set forth in col. 3, lines 23 – 41.

It would have been obvious to one of ordinary skill in the art to provide the ostomy appliance of Leise with a stiffening element as taught by Thomas because the use of such facilitates adhesion and/or reduces skin irritation as taught by Thomas in col. 3, lines 16 – 41.

With reference to claims 5 and 9 – 10, see col. 3, lines 16 – 41 and figure 3 of Thomas.

With respect to claim 16, see the rejection of claim 4.

### ***Response to Arguments***

Applicant's arguments filed October 27, 2009 have been fully considered but they are not persuasive.

Inasmuch as the applicant has provided a "one piece" ostomy device (i.e., bag and wafer), the examiner contends that Leise in view of '647 provides the same.

Furthermore, it is noted that the use of the open ended language "comprising", allows for the inclusion of additional elements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/  
Primary Examiner, Art Unit 3761